Notice of Allowability	Application No.	Applicant(s)	
	10/630,384	SCHAUDIES ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *12/19/2005*.

2. ☒ The allowed claim(s) is/are *16-63,80-124,136-142 and 144-147*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

JEFFREY FREDMAN
PRIMARY EXAMINER
1/25/06

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jamie Greene on January 20, 2006.

The application has been amended as follows:

Claims 125, 127-130 and 143 were cancelled without prejudice towards further prosecution.

The following claims were amended as shown.

16. A method for detecting one or more biological entities in a sample, comprising:

(a) combining one or more nucleic acid sequences in a sample with multiple primers comprising randomized nucleotide sequences, said randomized sequences being sufficiently

randomized such that substantially all of the nucleic acid sequences of a biological entity are represented among amplification products;

(b) randomly amplifying the sample nucleic acid sequences to produce nucleic acid amplification products;

(c) combining the amplification products with an array of predetermined nucleic acid sequences including redundancies which redundancies comprise multiple distinct nucleic acids from the same target entity and such that at least a portion of the amplification products hybridize to the array; and

(d) detecting amplification products that hybridize to the array.

32. A method for detecting one or more biological entities in a sample, comprising:

(a) combining one or more nucleic acid sequences in a sample with multiple primers comprising randomized nucleotide sequences, said randomized sequences being sufficiently

randomized such that substantially all of the nucleic acid sequences of a biological entity are represented among amplification products;

(b) randomly amplifying the sample nucleic acid sequences to produce nucleic acid amplification products;

(c) combining the amplification products with an array of predetermined nucleic acid sequences including positive controls, negative controls and redundancies which redundancies comprise multiple distinct nucleic acids from the same target entity and such that at least a portion of the amplification products hybridize to the array; and

(d) detecting amplification products that hybridize to the array.

48. A method for detecting one or more biological entities in a sample, comprising:

(a) combining nucleic acid sequences in a sample with multiple primers comprising randomized nucleotide sequences, said randomized sequences being sufficiently

randomized such that substantially all of the nucleic acid sequences of a biological entity are represented among amplification products;

(b) randomly amplifying the sample nucleic acid sequences to produce nucleic acid amplification products;

(c) combining the amplification products with an array of predetermined nucleic acid sequences having a known spatial arrangement or relationship to each other and further comprising redundancies which redundancies comprise multiple distinct nucleic acids from the same target entity and such that at least a portion of the amplification products hybridize to the array; and

(d) detecting amplification products that hybridize to the array.

80. A method for detecting one or more biological entities in a sample, comprising:

(a) combining nucleic acid sequences in a sample with multiple primers comprising randomized nucleotide sequences, said randomized sequences being sufficiently

randomized such that substantially all of the nucleic acid sequences of a biological entity are represented among amplification products;

(b) randomly amplifying the sample nucleic acid sequences at each cycle of the polymerase chain reaction, to produce nucleic acid amplification products;

(c) combining the amplification products with an array of predetermined nucleic acid sequences including redundancies which redundancies comprise multiple distinct nucleic acids from the same target entity and such that at least a portion of the amplification products hybridize to the array and wherein the redundancies on the array further comprise more than one copy of the same nucleic acid sequence; and

(d) detecting amplification products that hybridize to the array.

96. A method for detecting one or more biological entities of a plurality of preselected biological entities potentially present in a sample, comprising:

(a) combining nucleic acid sequences in a sample with multiple primers comprising randomized nucleotide sequences, said randomized sequences being sufficiently

randomized such that substantially all of the nucleic acid sequences of a biological entity are represented among amplification products;

(b) randomly amplifying the sample nucleic acid sequences to produce nucleic acid amplification products;

(c) hybridizing the amplification products to an array of predetermined positions on the array in a predetermined pattern, wherein the nucleic acid seuqences at the predetermined positions characterize at least one of the plurality of preselected biological entities and wherein the array comprises redundancies which redundancies comprise multiple distinct nucleic acids from the same target entity and

(d) detecting amplification products that hybridize to the array.

141. A method for detecting one or more pathogens in a sample, wherein the pathogens are used for the production of biological weapons for terrorism or battlefield use, comprising:

(a) combining one or more nucleic acid sequences in a sample with multiple primers comprising randomized nucleotide sequences, said randomized sequences being sufficiently

randomized such that substantially all of the nucleic acid sequences of a biological entity are represented among amplification products;

(b) randomly amplifying the sample nucleic acid sequences to produce nucleic acid amplification products;

(c) combining the amplification products with an array of predetermined nucleic acid sequences including redundancies which redundancies comprise multiple distinct nucleic acids from the same target entity and such that at least a portion of the amplification products hybridize to the array; and

(d) detecting amplification products that hybridize to the array.

REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance: The claimed invention is drawn to a combination of randomized PCR followed by hybridization to an array. As discussed in the previous action, Peng teaches randomized PCR and Beattie teaches hybridization detection on an array. The claims as amended are allowable since they all have the requirement that there are redundancies which comprise multiple distinct nucleic acids from the same target entity and in view of the declaration filed 12/19/05 by Paul Schaudies. The claim amendment could be met by other prior art which teaches the use of multiple nucleic acids for targeting in hybridization. However, the declaration shows the significant result, which is unexpected by the cited prior art of Beattie and Peng, that increasing the redundancy provides a significant increase in the confidence of detection. The claims are all now commensurate in scope with this result since all of the claims incorporate the requirement that multiple redundant nucleic acids from the target are present on the array. Therefore, in balancing the suggestive power of the references against the new limitations in the claims and the evidence in the declaration, the claims are novel and unobvious over the cited prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
Primary Examiner
Art Unit 1637
1/25/06